

# Performance Summary

## RAPID'*E. coli* O157:H7 Method



### Introduction

RAPID'*E. coli* O157:H7 Agar is a chromogenic medium for the detection of *Escherichia coli* O157:H7 in selected foods. The RAPID'*E. coli* O157:H7 method allows the presumptive identification of *E. coli* O157:H7, including atypical strains. The medium uses a proprietary mixture of a chromogenic substrate, selective mix, and nutritive mix. The selectivity of the medium is increased by adding the selective agents novobiocin and potassium tellurite. Typical *E. coli* O157:H7 (sorbitol-negative and  $\beta$ -glucuronidase-negative) and atypical ( $\beta$ -glucuronidase-positive) strains present characteristic bright, bulging colonies measuring 1–2 mm, dark blue to black in color with a slight black precipitate around the edges of the colonies. Atypical sorbitol-positive strains produce a blue to turquoise color colony with a weak black precipitate around the edges. The RAPID'*E. coli* O157:H7 method has been rigorously tested and validated by internationally recognized validation agencies (Table 1).

**Table 1. Validations for the RAPID'*E. coli* O157:H7 method.**

Validation	Certificate Number
AOAC	PTM 060701
NF Validation	BRD 07/14–09/07

### Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *E. coli* O157:H7, while exclusivity studies test non-*E. coli* O157:H7 strains, including other *E. coli* non-O157 strains, to ensure there is no cross-reactivity. Exclusivity strains were enriched in Brain Heart Infusion Broth for 24 hr at  $41.5 \pm 1^\circ\text{C}$ . A target of 10–100 colony forming units (CFU) of each *E. coli* O157:H7 inclusivity strain was cultured in supplemented Modified Tryptic Soy Broth with Novobiocin for 18 hr at  $41.5 \pm 1^\circ\text{C}$ . All colonies were confirmed regardless of morphology. Results are shown in Table 2.

**Table 2. Results of inclusivity/exclusivity testing.**

Strains Tested	Positives Detected	Results
50 <i>E. coli</i> O157:H7 strains tested	50/50	100% inclusivity
36 non- <i>E. coli</i> O157:H7 strains tested	0/36	100% exclusivity

### Limit of Detection

Limit of detection (LOD<sub>50</sub>) is an estimation of the contamination level required to achieve positive detection in 50% of cases. This is measured by inoculating food matrices with *E. coli* O157:H7 strains and carrying out the validated enrichment and detection protocols (Table 3).

The average LOD<sub>50</sub> of the RAPID'*E. coli* O157:H7 method was determined to be 0.7 (0.5–1.0).

**Table 3. LOD<sub>50</sub> for the RAPID'*E. coli* O157:H7 method.**

Matrix/Strain Pair	LOD <sub>50</sub> , CFU/Sample Size (range)
Ground beef/ <i>E. coli</i> O157:H7	0.6 (0.4–1.1)
Raw milk/ <i>E. coli</i> O157:H7	0.8 (0.4–1.5)
Apple cider/ <i>E. coli</i> O157:H7	0.4 (0.2–0.7)
Deli salad/ <i>E. coli</i> O157:H7	1.2 (0.7–2.3)

### Method Comparison/Matrix Studies

Matrix testing is critical to demonstrating the performance of a method compared to the reference method with real-world food samples. The RAPID'*E. coli* O157:H7 method has been verified with external and internal testing on a wide variety of foods. No significant difference was found between the RAPID'*E. coli* O157:H7 method and the reference method for all matrices tested (Table 4).

**Table 4. Matrices tested with RAPID'E.coli O157:H7 method.**

Category	Matrices Tested
<b>Composite foods</b> RTE, RTRH, pastries and egg products	<p><b>RTE:</b> Deli salad, cabbage salad, tuna salad, ham sandwich, tabbouleh, chicken and pasta salad, rice and vegetable salad, celery salad, vegetables, Greek salad with tomatoes, salad with cheese, pork salad, potato salad, terrine, salmon and pasta salad, chicken salad, vegetable salad, tuna salad with tomatoes, coleslaw, pork and lentil salad, carrot melon soup</p> <p><b>RTRH:</b> Paella, pork, fish, mussels, cod, lentil sausage, potatoes, lasagna, spinach, veal, sausage, sausage with vegetables, couscous, turkey meat in cream sauce, chicken, beef with tomatoes, beef pasta, cod brandade, pork ribs with honey, spicy chicken</p> <p><b>Pastries and egg products:</b> Omelet, potato omelet, whipped cream, floating island dessert (meringue with cream), egg tart, pastry, tortilla, flan, chocolate éclair, raspberry tart</p>
<b>Meat products</b> Raw and RTC, RTE and RTRH, deli	<p><b>Raw and RTC:</b> Beef trim, ground beef, seasoned beef, seasoned ground beef, frozen seasoned beef, veal meat, frozen veal, ground veal, pork trim, pork meat, frozen pork, seasoned pork, seasoned ground pork, chicken meat, frozen poultry, frozen chicken, turkey meat, veal carcass, beef carcass</p> <p><b>RTE and RTRH:</b> Sausage, bacon, smoked bacon, seasoned meatballs, couscous meal, cooked beef</p> <p><b>Deli:</b> Pâté, duck meat, ham</p>
<b>Dairy products</b> Raw milk and products, heat processed	<p><b>Raw milk and products:</b> Raw milk, raw cow milk cheese, raw goat milk cheese</p> <p><b>Heat processed:</b> Processed cheese, ewe milk yogurt, cottage cheese, yogurt (with and without fruit), fermented milk, fresh cream</p>
<b>Produce</b> Fresh, processed	<p><b>Fresh:</b> Spinach, mixed vegetables, carrots, butter beans, green beans, brussels sprouts, zucchini, cabbage, green pepper, broccoli</p> <p><b>Processed:</b> Grated carrots, grated cabbage, salad, powdered onion, cut pineapple, cut fruit, broccoli puree, artichoke puree, blackberry puree, mango puree, white peach puree, strawberry puree, pear and peach puree, zucchini soup, banana pumpkin kiwi soup, orange banana carrot soup, raspberry sauce, gazpacho, watercress cream, vegetable soup, eggplant soup, zucchini soup, orange juice, apple juice, mango juice, apple cider, dairy fruit juice, pear applesauce, prune applesauce, strawberry applesauce, vanilla applesauce, tomato sauce, sauerkraut, fermented olives, fermented black radish, fermented red pepper, fermented carrots, fermented red cabbage, fermented white cabbage, fermented vegetables, pickles</p>

RTC, ready to cook; RTE, ready to eat; RTRH, ready to reheat.

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